CLAIMS

1. A controlled release pharmaceutical formulation characterised in that it comprises a pellet core from which a low dose active substance freely soluble in water can be released in a controlled manner independently from pH thereby providing a lower biological variability.
2. A controlled release pharmaceutical formulation characterised in that it comprises a pellet core comprising at least one insoluble permeable polymer and at least one surfactant and optionally other excipients.
3. The pharmaceutical formulation according to claim 2 wherein said insoluble permeable polymer is selected from the group of acrylic polymers or alkylcelluloses or hydroxyalkylcelluloses or a combination thereof.
4. The pharmaceutical formulation according to claim 3 wherein said insoluble permeable polymer is a copolymer of ethylacrylate and methylmethacrylate in a ratio of 2:1, optionally being in the form of a 30 % aqueous dispersion.
5. The pharmaceutical formulation according to claims 1-4 wherein the diameter of the pellet cores is from about 0.5 to about 1.25 mm.
6. The pharmaceutical formulation according to claims 1-5 wherein said pellet core is coated with a gastroresistant and/or release controlling coating.
7. The pharmaceutical formulation according to claim 6 wherein the mass of the applied coating is from about 5 to about 10 % relative to the mass of dried pellet cores.
8. The pharmaceutical formulation according to claim 7 wherein the mass of the applied coating is from about 5 to about 8 % relative to the mass of dried pellet cores.
9. The pharmaceutical formulation according to claims 6-8 wherein the coating comprises at least one polymer soluble at pH values higher than about 5.5 and at least one polymer with a pH independent solubility.
10. The pharmaceutical formulation according to claim 9 wherein said polymer soluble at higher pH values is an anionic copolymer of methacrylic acid and ethylacrylate and said polymer with pH independent solubility is a copolymer of ethylacrylate and methylmethacrylate.

11. The pharmaceutical formulation according to claims 1-10 wherein the pellets are filled into capsules or sachets or compressed into tablets.
12. The pharmaceutical formulation according to claims 1-11 wherein the pellet cores are prepared by using the methods of extrusion and spheronization.
13. The pharmaceutical formulation according to any of the preceding claims wherein the freely soluble low-dose active substance is tamsulosin or a pharmaceutically acceptable salt thereof.
14. A process for the preparation of pharmaceutical formulations according to claims 1-13 characterised in that it comprises the following steps: preparation of the blend of the ingredients for the core, granulation, extrusion and spheronization, drying and optionally coating.
15. Use of the pharmaceutical formulation according to claim 13 for the preparation of a medicament for the treatment of benign prostatic hyperplasia.